K040637

AUG - 6 2004

SECTION 17: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

17.1: ADMINSTRATIVE INFORMATION

Name and Address

Submitted by:	Cardiac Science Incorporated 5474 Feltl Road Minnetonka, MN 55343
Contact Person:	Kenneth F. Olson
Telephone No.:	952-939-4181
Facsimile No.:	952-939-4191
Email:	kolson@cardiacscience.com
Date Prepared:	March 5, 2004

17.2: DEVICE INFORMATION

Common or Usual Name:	Automatic External Defibrillator
Trade Name:	Powerheart® Automatic External Defibrillator G3Pro

17.3: DEVICE CLASSIFICATION

Classification Name:	Automated External Defibrillator
	21 CFR 870.5310 MKJ
	Device Class: III

17.4: DEVICE DESCRIPTION

The Powerheart® AED G3Pro is a portable, battery-operated, semi-automatic, low power DC defibrillator. The device is designed to diagnose and monitor the patient's cardiac rhythm and deliver the shock energy as required. The Powerheart® AED G3Pro also has an ECG display and manual override for advanced users. The device in this submission is equivalent to the current Powerheart® AED and accessories in commercial distribution that was cleared under premarket 510(k) notifications K022929, K011901, K982710 and K031987. The reason for this premarket notification is to introduce the semi-automatic

17.6: IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Cardiac Science	Powerheart AED	K031987	07/30/2003
Philips Medical Systems	Heartstream FR2	K014157 K013425	01/17/2002 01/14/2002

17.7: SUBSTANTIAL EQUIVALENCE

The Powerheart® AED G3Pro covered by this submission is substantially equivalent to other legally marketed automatic external defibrillators. Specifically, the Powerheart® AED G3Pro that is the subject of this premarket notification is equivalent to the current Powerheart® AED G3 in commercial distribution with the exception of having the ECG display and manual override options. The Powerheart AED G3Pro is substantially equivalent to the ECG display and manual override features of the Philips Medical Systems Heartstream FR2 AED.

17.8 PERFORMANCE TESTING

The Powerheart® AED G3Pro is subjected to performance software and hardware evaluations in accordance with FDA guidelines and industry standards. The results of the testing showed that the device modifications had no affect on the safety or effectiveness of the device. The Powerheart® AED G3Pro was found to perform as intended.

17.9 CONCLUSIONS

Cardiac Science has demonstrated through its evaluation and testing of the Powerheart® AED G3Pro that the device is equivalent to the current Powerheart® AED and the Philips Medical Systems Heartstream FR2 AED. The proposed Powerheart® AED G3Pro is equivalent with respect to indications for use, technological characteristics, materials, and software algorithm as the current commercially distributed Powerheart® AED and the Heartstream AED. This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2009

Cardiac Science, Inc.
c/o Mr. Kenneth F. Olson
Chief Technology Officer
5474 Feltl Road
Minnetonka, MN 55343

Re: K040637
Trade/Device Name: Powerheart Automatic External Defibrillator G3Pro
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (Three)
Product Code: MKJ
Dated: June 22, 2004
Received: June 23, 2004

Dear Mr. Olson:

This letter corrects our substantially equivalent letter of August 6, 2004.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

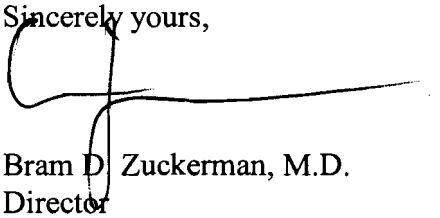
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K040637

Device Name: Powerheart® Automatic External Defibrillator G3 Pro

Indications For Use:
The Powerheart® AED G3 Pro, model 9300P, is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

When a patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the Powerheart AED G3 Pro should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. The therapy should not be delayed to determine the patient's exact age or weight.

At the discretion of emergency care personnel, the G3Pro with ECG display enabled can also be used with the Model 5111 ECG Patient Cable to display the rhythm of a responsive or breathing patient, regardless of age. The G3Pro and ECG Patient Cable system provides a non-diagnostic display for attended patient monitoring. While connected the G3Pro ECG Patient Cable, the G3Pro evaluates the patient's ECG and disables its shock capability.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040637